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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ANDREW CLARK, CARLOS SCHULER, and STEVE PABOOJIAN

Appeal 2008- 2508
Application 09/414,384
Technology Center 3700

Decided: September 19, 2008

Before ERIC GRIMES, RICHARD M. LEBOVITZ, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an aerosolized drug delivery device. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

BACKGROUND

> [P]ulmonary drug delivery relies on inhalation of an active agent formulation by the patient so that active drug within the

> dispersion can reach the distal (alveolar) regions of the lung. This may be accomplished using a patient driven device where it is the inspiratory flow that aerosolizes the active agent formulation or using a drug dispersion or aerosol device that uses a compressed gas or propellant to aerosolize and deliver the active agent formulation.

(Specification 1).

The Specification discloses "a device for delivering an aersolized active agent formulation to the lungs of a human patient" that "provide[s] the aerosolized active agent formulation with high flow resistance for an initial period followed by a period of lower flow resistance" (*id.* at 3-4).

DISCUSSION

1. CLAIMS

Claims 21-36 are pending and on appeal. Claim 21 is representative and reads as follows:

Claim 21: A device for controlling the delivery of an aerosolized active agent to the lungs of a human patient, said device comprising

a valve that provides a high flow resistance of at least 0.4 (cm $H_2O)^{1/2}$ / SLM at the onset of the patient's inhalation and

that subsequently opens to provide a lower flow resistance, wherein the lower flow resistance allows for a higher flow rate through the device.

2. OBVIOUSNESS

Claims 21-36 stand rejected under 35 U.S.C. § 103 as obvious in view of Howe.[1] The Examiner relies on Howe as disclosing a device meeting all the limitations of claim 21 except for the specific initial flow resistance (Answer 3-4).

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[1] Howe et al., US 5,655,520, Aug. 12, 1997

The Examiner further finds that the valve of Howe provides "a high flow resistance at the onset of a patient's inhalation by closing at least partially (fig. 3b) against an inhalation flow rate that exceeds the intended flow rate and subsequently opens (fig. 3a) thereby providing a lower flow resistance against an inhalation flow rate that falls below the maximum intended flow rate" (*id.* at 3). The Examiner concludes that modifying Howe's valve to provide the initial flow rate recited in claim 21 would have been "an obvious matter of design choice" (*id.* at 3-4).

Appellants argue that Howe does not teach "a valve that provides a high flow resistance at the onset of the patient's inhalation and that subsequently opens to provide a lower flow resistance, wherein the lower flow resistance allows for a higher flow rate through the device" (Appeal Br. 4). Appellants further argue that Howe's "flow regulator valve provides a maximum opening, i.e. a minimum flow resistance, when a patient is inhaling weakly and a minimum opening, i.e. a maximum flow resistance, when a patient is inhaling strongly" (*id.*). Appellants argue that "Howe et al is concerned with maintaining a consistent flow rate while Appellant's valve is concerned with providing an altered flow rate" and therefore Howe does not teach the valve recited in claim 21 (*id.*).

We agree with Appellants that the cited reference does not support a prima facie case of obviousness. In particular, we agree that the Examiner has not adequately explained how the reference would have suggested "a valve that provides a high flow resistance …at the onset of the patient's inhalation and that subsequently opens to provide a lower flow resistance,

wherein the lower flow resistance allows for a higher flow rate through the device."

Howe discloses a nebulizer for pulmonary drug delivery (Howe, col. 1, ll. 16-20). The disclosed nebulizer contains a "variable diameter input valve [that] reduces its orifice size by means of collapsing flexible walls" (*id.* at col. 1, ll. 59-60). The "valve's flexible walls collapse in proportion to the pressure differential between ambient and nebulizer chamber pressures," with the result that when a patient breathes in strongly, the walls collapse and a smaller orifice is formed but when a patient breathes in weakly, the walls and orifice remain open (*id.* at col. 1, l. 62 to col. 2, l. 8). In other words, Howe discloses that "[o]verall within the normal limits of human breathing variations, the nebulizer's throughput flow rate through the valve's flexible walls remains constant" (*id.* at col. 2, ll. 9-11).

Thus, Howe's valve does not meet the limitation of providing a high initial flow resistance at onset of inhalation and subsequently opening to provide a lower flow resistance and higher flow rate. If the "onset of the patient's inhalation" is interpreted to mean before inhalation has begun, Howe's valve would be fully open at that point and would not open further, i.e. provide lower resistance at a point in time after inhalation has begun, as required by claim 21. And, even if the "onset of the patient's inhalation" were somehow interpreted to mean some point after inhalation has begun, Howe's valve is designed to provide a constant flow rate and thus would not allow a higher flow rate through the device at a point in time after inhalation has begun, as required by claim 21.

Thus, even considering two alternative interpretations of the term, "after the onset of inhalation," the Examiner has not adequately shown that the Howe device includes or would have suggested "a valve that provides a high flow resistance . . . at the onset of the patient's inhalation and that subsequently opens to provide a lower flow resistance, wherein the lower flow resistance allows for a higher flow rate through the device," as recited in claim 21.

We therefore agree with Appellants that the Examiner has not made out a prima facie case of obviousness based on the cited references. The rejection of claim 21 is reversed. Claims 22-36 also require a valve that opens after onset of inhalation to provide a lower flow resistance and higher flow rate. The rejection of claims 22-36 is therefore reversed as well.

REVERSED

dm

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